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Datasheet for the decision of 18 July 2017

Case Number: T 0782/16 - 3.3.07

Application Number: 10179085.5

Publication Number: 2292219

IPC: A61K9/70, A61K31/27

Language of the proceedings: EN

Title of invention:
Transdermal therapeutic system for the administration of rivastigmine

Patent Proprietor:
Novartis AG
Novartis Pharma GmbH
LTS LOHMANN Therapie-Systeme AG

Opponents:
Easypharm GmbH & Co KG
Acino Pharma AG
Alvogen IPCo S.àr.l
STADA Arzneimittel AG
neuraxpharm Arzneimittel GmbH
SK Chemicals Co., Ltd.
Generics [UK] Limited
Actavis Group PTC ehf
Genericon Pharma Gesellschaft m.b.H.
PENTAFARMA, Sociedade Técnico-Medicinal, SA
TECNIMEDE ESPAÑA Industria Farmacéutica, S.A.
Dr. Reddy's Laboratories (UK) Limited/ betapharm Arzneimittel GmbH
Biogaran

Headword:
Rivastigmine/NOVARTIS

Relevant legal provisions:
EPC Art. 76(1), 123(2)
EPC R. 103(1)(a)

Keyword:
Divisional application - added subject-matter (yes)
Amendments - added subject-matter (yes)
Reimbursment of appeal fee (no)

Decisions cited:
G 0002/10

Catchword:
Reasons, points 4.1.1 to 4.1.3

Europäisches Patentamt
European Patent Office
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Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0782/16 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 18 July 2017

Appellant: (Patent Proprietor 1)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Appellant: (Patent Proprietor 2)	Novartis Pharma GmbH Brunner Strasse 59 1230 Wien (AT)
Appellant: (Patent Proprietor 3)	LTS LOHMANN Therapie-Systeme AG Lohmannstrasse 2 56626 Andernach (DE)
Representative:	Warner, James Alexander Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Opponent 1)	Easypharm GmbH & Co KG Perlhofgasse 2/2 2372 Giesshübl (AT)
Respondent: (Opponent 2)	Acino Pharma AG Dornacherstr. 114 4147 Aesch (CH)
Respondent: (Opponent 3)	Alvogen IPCo S.àr.l 412F, Route d'Esch 2086 Senningerberg (LU)

Representative:
Raggers, René John
Exter Polak & Charlouis B.V.
P.O. Box 3241
2280 GE Rijswijk (NL)

Respondent:
(Opponent 4)
(no longer a party to the proceedings due to the withdrawals of the appeal and of the opposition by letter of 4 November 2016)

Respondent:
(Opponent 5)
STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel (DE)

Representative:
Hamm & Wittkopp Patentanwälte PartmbB
Jungfernstieg 38
20354 Hamburg (DE)

Respondent:
(Opponent 6)
neuraxpharm Arzneimittel GmbH
Elisabeth-Selbert-Str. 23
40764 Langenfeld (DE)

Representative:
Kossak, Sabine
Harmsen - Utescher
Rechtsanwälte - Patentanwälte
Neuer Wall 80
20354 Hamburg (DE)

Respondent:
(Opponent 7)
SK Chemicals Co., Ltd.
310 Pangyo-ro
Bundang-gu, Seongnam-si
Gyeonggi-do 463-400 (KR)

Representative:
Alt, Michael
Bird & Bird LLP
Maximiliansplatz 22
80333 München (DE)

Respondent:
(Opponent 8)
Generics [UK] Limited
(trading as Mylan)
Albany Gate
Darkes Lane
Potters Bar
Hertfordshire EN6 1AG (GB)

Representative:
Gillard, Richard Edward
Elkington and Fife LLP
Thavies Inn House
3-4 Holborn Circus
London EC1N 2HA (GB)

Respondent: (Opponent 9)
Actavis Group PTC ehf
Reykjavikurvegi 76-78
220 Hafnarfjördur (IS)

Representative:
Murray, Adrian D'Coligny
Pinsent Masons LLP
30 Crown Place
Earl Street
London EC2A 4ES (GB)

Respondent: (Opponent 10)
Genericon Pharma Gesellschaft m.b.H.
Hafnerstrasse 211
8054 Graz (AT)

Representative:
Keschmann, Marc
Haffner und Keschmann
Patentanwälte GmbH
Schottengasse 3a
1014 Wien (AT)

Respondent: (Opponent 11)
PENTAFARMA, Sociedade Técnico-Medicinal, SA
Rua da Tapada Grande, n° 2
Abrunheira
2710-089 Sintra (PT)

Respondent: (Opponent 12)
TECNIMEDE ESPAÑA Industria Farmacéutica, S.A.
Avda. de Bruselas, n° 13. 3°D
Polígono Arroyo de la Vega
28108 Alcobendas Madrid (ES)

Representative:
Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München (DE)

Respondent: (Opponent 13)
Dr. Reddy's Laboratories (UK) Limited/ betapharm Arzneimittel GmbH
6 Riverview Road/ Kobelweg 95
Beverley/Augsburg
East Yorkshire HU17 0LD GB/86156 DE (GB)

Representative:
Best, Michael
Lederer & Keller
Patentanwälte Partnerschaft mbB
Unsöldstrasse 2
80538 München (DE)

Respondent: (Opponent 14)
Biogaran
15 boulevard Charles de Gaulle
92700 Colombes (FR)

Representative: Casalonga
Casalonga & Partners
Bayerstraße 71/73
80335 München (DE)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 15 March 2016 revoking European patent No. 2292219 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: A. Usuelli
I. Beckedorf

Summary of Facts and Submissions

I. European patent No. 2 292 219, based on European application 10179085.5 filed as a divisional of the earlier application 06816633.9, was granted on the basis of one claim reading as follows:

"1. Rivastigmine for use in a method of preventing, treating or delaying progression of dementia or Alzheimer's disease, wherein the rivastigmine is administered in a TTS and the starting dose is that of a bilayer TTS of 5 cm^2 with a loaded dose of 9 mg rivastigmine, wherein one layer:
has a weight per unit area of 60 g/m2 and the following composition:
- rivastigmine free base 30.0 wt%
- Durotak® 387-2353 (polyacrylate adhesive) 49.9 wt%
- Plastoid® B (acrylate copolymer) 20.0 wt%
- Vitamin E 0.1 wt%
and wherein said layer is provided with a silicone adhesive layer having a weight per unit area of 30 g/m2 according to the following composition:
- Bio-PSA® Q7-4302 (silicone adhesive) 98.9 wt%
- Silicone oil 1.0 wt %
- Vitamin E 0.1 wt%".

II. The patent was opposed on multiple grounds, including that its subject-matter extended beyond the content of the application as filed and beyond the content of the earlier application.

III. By decision posted on 15 March 2016 the patent was revoked. The decision was based on a main request and three auxiliary requests. The main request, auxiliary request 1 and auxiliary request 3 were filed on

15 October 2015. Auxiliary request 2 was the patent as granted.

Each request consisted of a single claim relating to rivastigmine administered via a transdermal therapeutic system (TTS), wherein said TTS was characterised by a starting dose defined as in claim 1 of the patent as granted (see point I above).

The following document was referred to in the appealed decision:

B29: WO2007/064407 - parent application of the patent.

IV. In the appealed decision, the opposition division held that claim 1 of the main request related to any TTS providing the same starting dose as the specific TTS of 5 cm^2 referred to in the claim. The subject-matter of the claim had no basis in document B29. In particular, this subject-matter could be derived neither from example IV nor from page 11, contrary to what the patent proprietors argued. Thus, the main request did not comply with Articles 123(2) and 76(1) EPC. These conclusions applied to the subject-matter of the auxiliary requests too.

V. The patent proprietors (hereinafter: the appellants) filed an appeal against that decision. With the statement setting out the grounds of appeal filed on 25 July 2016, the appellants submitted seven auxiliary requests.

Claim 1 of auxiliary request 1 differed from claim 1 of the patent as granted by the addition of expression "once a day" before the words "starting dose".

Claim 1 of auxiliary request 2 differed from claim 1 of the patent as granted in that the feature "dementia or Alzheimer's disease" had been replaced by "mild to moderate Alzheimer's disease".

Claim 1 of auxiliary request 3 differed from claim 1 of the patent as granted in that it included both amendments introduced in auxiliary requests 1 and 2.

Claim 1 of auxiliary requests 4 to 7 was based on claim 1 of the granted patent and of the first three auxiliary requests, respectively, but included the following feature, at the end of the claim:

"an AUC_{24h} of 25 to 450 ng*h/mL after repeated once daily administration provided".

VI. Replies to the appeal of the patent proprietors were submitted by opponents 2, 3, 5 to 8, 10, 13 and 14 (hereinafter: respondents 2, 3, 5 to 8, 10, 13 and 14).

By letter of 4 November 2016, opponent 4 withdrew its opposition.

VII. Oral proceedings were held on 18 July 2017. For information on the course of the oral proceedings, reference is made to the minutes.

VIII. The appellants' arguments can be summarised as follows:

B29 contained embodiments which were directed to a "structural invention" relating to a TTS with a particular adhesive layer but not restricted to rivastigmine, and other embodiments directed to a "use invention" relating to TTSs that provided specific rivastigmine release profiles but which were not

limited by any further structural features. The "structural invention" and the "use invention" were clearly presented in B29 as separable. The skilled team, with competence both in medicine and in the field of pharmaceutical formulations, would have concluded that use embodiments relating to rivastigmine TTSs need not be limited to TTSs having a particular structure. This applied in particular to the disclosure of example IV and to the first paragraph of page 11. Example IV disclosed a study in which a group of patients were treated either with capsules of rivastigmine or with a TTS containing rivastigmine. At the beginning of the study, the patients treated with the TTS inherently received a starting dose. This would have been clear to a skilled person despite the fact that it was not spelled out *expressis verbis*. In comparing tables 1 and 2 of example IV, the skilled team would have immediately noted that the AUC_{24h} for the TTS starting dose was approximately four times higher than for the oral starting dose. Furthermore, as explained on page 9 of B29, the skilled team knew that the same starting dose could be obtained with other TTSs, different from the specific TTS used in the study of example IV. Accordingly, it was permissible to base a claim on the same starting dose as delivered by the TTS of example IV but with no restriction on the structure of the TTS. The first paragraph of page 11 containing an explicit reference to rivastigmine was a further embodiment of the "use invention". This paragraph was not restricted to any specific TTS. The skilled team would have linked the reference to a "higher starting dose" to the starting dose of the TTS used in example IV, since no other starting dose was mentioned in B29. The combination of the passage on page 11 and example IV provided a basis for the subject-matter of claim 1.

IX. The respondents argued *inter alia* that example IV of B29 described a study concerning the pharmacokinetic properties of a specific rivastigmine TTS named TTS#2. The results disclosed in this example were linked to the use of this specific TTS. There was no basis for a generalisation to cover any TTS providing the same starting dose as TTS#2. The passage on page 11 did not contain any link to example IV. Even assuming that the skilled person would have combined page 11 and example IV, he would have nonetheless concluded that it was possible to increase the starting dose of rivastigmine by the use of the specific TTS of example IV. Accordingly, the subject-matter of claim 1 could not be directly and unambiguously derived from B29.

X. The appellants requested that the decision under appeal be set aside and that the case be remitted to the opposition division for consideration of any grounds other than Article 100(c) EPC on the basis of the patent as granted or on the basis of one of the seven auxiliary requests filed with the statement setting out the grounds of appeal on 25 July 2016, and that the appeal fee be reimbursed.

XI. Respondents 2, 3, 5, 6, 7, 8, 10, 11, 12, 13 and 14 requested that the appeal be dismissed.

Respondents 2 and 13 furthermore requested that auxiliary requests 4 to 7 not be admitted into the appeal proceedings.

Reasons for the Decision

MAIN REQUEST (GRANTED PATENT)

Articles 76(1) and 123(2) EPC

1. In line with the approach taken in the appealed decision and by the parties, the Board will assess compliance with the requirements of Articles 76(1) and 123(2) EPC by comparing the subject-matter of claim 1 with the disclosure of document B29, i.e. the publication of the parent application. This document is identical to the parent application as originally filed and is incorporated in the application underlying the patent in suit as originally filed.

2. The subject-matter of the patent

2.1 The patent contains a single claim drafted in the format of a purpose-limited product claim pursuant to Article 54(5) EPC (see point I above). In point 3 of its decision, the opposition division construed claim 1 as granted *"as encompassing any TTS as long as it comprises rivastigmine and as long as in the use of claim 1 there is provided a certain "starting dose". The amount of the starting dose is corresponding to that provided by the TTS having the structural features as indicated in claim 1. These structural features, however, are intended to define the starting dose only, not the TTS employed in the medical use of claim 1 as such".*

The Board agrees with this interpretation of claim 1. It is noted that none of the parties proposes a different reading of the claim.

3. The disclosure of B29

3.1 In their written submissions and during the oral proceedings, the appellants presented some general observations concerning the content of B29 as a preliminary remark for a correct interpretation of this document and in particular of the passages supposedly providing the basis for the subject-matter of claim 1, namely example IV and the first paragraph of page 11 (see below).

The Board therefore finds it appropriate to analyse the general disclosure of B29 before considering the specific passages of this document that supposedly provide a basis for the subject-matter of claim 1.

3.2 The appellants emphasise that B29 is a so-called omnibus application containing two separable embodiments. The first ("the structural invention") relates to a particular TTS which is defined in claim 1 and which is not restricted to rivastigmine, and the second ("the use invention") relates to TTSs that provide specific rivastigmine release profiles but which are not limited by any further structural features.

3.3 The Board observes that the description of B29 discloses, from paragraph 5 of page 1 to paragraph 2 of page 2, a number of objectives of the invention. The third paragraph of page 2 then states that these objectives are achieved by a TTS as defined in claim 1, which is characterised by the presence of an adhesive layer with a silicone polymer. This TTS represents, in the Board's view, the central aspect of the invention disclosed in B29. Indeed, the eighth paragraph of page 2 states that "*[t]ests with active ingredients for the*

treatment of Alzheimer's disease have surprisingly shown that a line of silicone adhesive can be applied to a poorly adhesive reservoir matrix, thus significantly increasing the adhesive properties of the preparation without affecting the thermodynamic properties of the TTS". On the basis of this finding, the invention disclosed in B29 provides a TTS comprising (a) a backing layer, (b) a reservoir layer and (c) an adhesive layer with a silicone polymer (page 3, lines 5 to 7 and claim 1). TTS#2, the patch used in the clinical test disclosed in example IV is a TTS with these structural features.

Thus, what the appellant defines as the structural invention, represents in the Board's view the core of the disclosure of B29.

3.4 The appellants mentioned various passages of B29 as representative of the "use invention", for instance the third paragraph on page 3 (*"The present invention is further related to a method for substantially improving the efficacy and tolerability of rivastigmine, comprising application of a TTS in the range of 2 to 50 cm^2, said formulation providing a mean maximum plasma concentration of about 1 to 30 ng/mL..."*) or the fourth paragraph on page 9 (*"The invention further provides a TTS comprising as active ingredient rivastigmine...having a mean maximum plasma concentration of about 1 to 30 ng/ml...and an AUC 24h of about 25 to 450 ng*h/mL ..."*).

In the Board's view, the skilled audience could well attribute all these passages to the "structural invention", i.e. it could consider the TTSs referred to in these paragraphs to be the same TTSs defined in claim 1 or on page 3 of B29. Indeed, B29 does not refer

to any other type of TTS. Furthermore, the experimental data concerning the plasma concentration of rivastigmine disclosed in the patent (see example IV and figures 3 and 4) relate to tests carried out using TTS#2, i.e. a TTS according to claim 1 of B29. Hence, the specific rivastigmine release profiles, that characterise the "use invention" according to the appellants are in fact achieved by the use of the TTSs of claim 1. Moreover, as discussed above, on pages 1 and 2 B29 describes a number of objectives of the invention which include methods of treatment based on the administration of rivastigmine. The sole solution proposed in B29 to achieve these objectives is "by a TTS as defined in claim 1" (page 2, line 8).

Thus, the Board is not convinced that B29 relates to two groups of independent inventions, namely a "structural invention" and a "use invention".

3.5 In any case, the Board sees no need to establish whether one or more independent inventions are disclosed in B29. What matters in the assessment of compliance with Articles 76(1) and 123(2) EPC is to establish whether the subject-matter of the patent can be derived in a clear and unambiguous manner from the disclosure of B29.

The appellants do not disputed that B29 does not explicitly disclose the subject-matter of claim 1. In their opinion, however, this subject-matter can be derived from document B29 in two different ways: based on the disclosure of example IV (defined by the appellants as derivation#1) and on the first paragraph of page 11 (defined by the appellants as derivation#2). These are discussed below.

4. Possible derivations of the subject-matter of claim 1

4.1 Derivation#1

4.1.1 Example IV describes a study carried out on patients with mild to moderate Alzheimer's disease. The patients received either an oral formulation of rivastigmine (Exelon® capsules) or a transdermal one. The transdermal formulation is the patch TTS#2 which is described in example I of B29. The study comprised four periods with an increasing dosage of the active ingredient. In the first period the patients were treated either with 1.5 mg bid (twice a day) of Exelon® or with TTS#2 of 5 cm^2. In the second to fourth periods the patients were treated with increasing doses of rivastigmine: the patients enrolled for the oral therapy received 3 mg, 4.5 mg and 6 mg bid Exelon®; those in the transdermal therapy were treated with TTS#2 patches of 10 cm^2, 15 cm^2 and 20 cm^2. Tables 1 and 2 provide a summary of the pharmacokinetic parameters of rivastigmine following capsule administration (Table 1) or the TTS#2 application (Table 2). The pharmacokinetic parameters include the maximum serum concentration (C_{max}), the time at which the C_{max} is observed (t_{max}), the half-life ($t_{1/2}$) and the 24-hour area under the concentration-time curve (AUC_{24h}). The data relate to the four periods.

4.1.2 The Board notes that example IV does not contain any reference to a TTS other than the patch TTS#2 used on the patients. Nor is there anything in this example to indicate using a TTS other than TTS#2.

4.1.3 The appellants argue that a skilled team, composed of experts in medicine and in the field of pharmaceutical formulations, would have noted that the AUC_{24h} provided

by the TTS#2 of 5 cm^2 was approximately four times higher than the AUC_{24h} obtained with 1.5 mg twice a day of Exelon®. They would have then considered using any TTS providing the same dose as the TTS#2 of 5 cm^2.

In the Board's view, the appellants' reasoning is not in line with the "gold" standard required for the assessment of Articles 123(2) and 76(1) EPC. This standard requires that the subject-matter of an amended claim (or of a claim of a divisional application) be based only on what the skilled person would directly and unambiguously derive from the application as originally filed (or from the earlier application; see G 2/10, point 4.3 of the Reasons). For a correct application of this standard, a distinction needs to be made between subject-matter which is disclosed either implicitly or explicitly in the original (or earlier) application and therefore can be directly derived from it, and subject-matter which is the result of an intellectual process, in particular a complex one, carried out on what is disclosed.

The intellectual process undertaken by the appellants to reach claim 1 from example IV comprises the steps of:

(a) singling out from all the data disclosed in tables 1 and 2 the AUC_{24h} of the TTS#2 of 5 cm^2 and of the capsules of 1.5 mg;
(b) comparing these two pieces of data;
(c) formulating the idea of using any TTS that is capable of providing the same rivastigmine dose as the TTS#2 of 5 cm^2.

In this context the Board notes that the AUC_{24h} values obtained with the TTS#2 patches of 10 cm^2, 15 cm^2 and 20 cm^2 are also much higher than the AUC_{24h} values obtained with the capsules of 3 mg, 4.5 mg and 6 mg bid

Exelon®. Example IV is silent about the relevance of the AUC_{24h} of the TTS#2 of 5 cm^2. There is also no indication to use a TTS different than TTS#2 but capable of providing the rivastigmine release of the TTS#2 of 5 cm^2. In other words, the clinical study described in example IV relates to the application of a specific patch, namely TTS#2.

The appellants' reasoning is therefore based on an intellectual processing of the subject-matter disclosed in the original (or earlier) application rather than a direct and unambiguous derivation as required by the "gold" standard. No matter whether or not such processing is based on obvious considerations, such a reasoning cannot be used to justify the compliance with Articles 76(1) and 123(2) EPC.

4.1.4 The arguments put forward by the appellants in relation to the information disclosed on page 9 of B29 do not invalidate the above conclusions.

Paragraph 4 of page 9 states that the invention provides a TTS comprising rivastigmine "*having a mean maximum plasma concentration of about 1 to 30 ng/ml...and an AUC 24h of about 25 to 450 ng*h/mL*". The following paragraph explains that a skilled person would be familiar with "*how to produce a TTS having the above defined plasma profiles*" and how a patch could be modified in order to obtain the desired plasma profile. In the appellants' view, the skilled audience would link these passages to example IV, finding an indication to provide patches other than the TTS#2 that are nonetheless capable of providing the same dose as the TTS#2 of 5 cm^2.

4.1.5 The Board is not persuaded by this argument. Page 9 does not contain any reference to example IV. Nor is there any indication that the instructions on how to produce a TTS providing a certain plasma profile should be applied to produce any TTS with the same rivastigmine release profile as the TTS#2 of 5 cm^2.

The skilled audience would read the passages on page 9 referred to by the appellants in relation to the main subject of the invention, namely the provision of the TTS described on page 3, lines 5 to 7 (see point 3.3 above). In this respect it is noted that the passage on page 9 refers to the possibility of modifying the adhesive layer. Whereas the TTS of claim 1 contains an adhesive layer, not every TTS does. The skilled team would therefore consider the general instructions of page 9 not to constitute an indication to produce any TTS, regardless of its structure. Rather, they are instructions on how to prepare or modify TTSs of the type described on page 3 in order to obtain such plasma profiles. Indeed, the sole pharmacokinetic data disclosed in B29 are those in example IV for TTS#2, i.e. a TTS comprising a backing layer a reservoir layer and an adhesive layer with a silicone polymer, just like the TTS defined on page 3.

4.1.6 It follows that example IV does not constitute a valid basis for a claim directed to any TTS providing the same rivastigmine release as the TTS#2 of 5 cm^2.

4.2 Derivation#2

4.2.1 The appellants' proposed alternative way to derive the subject-matter of claim 1 from the disclosure of B29 is based on the first paragraph of page 11. This passage of the description indicates that "*the TTS of the*

invention...may allow a higher starting dose". In the appellants' view, the skilled team would link this passage to the starting dose of example IV since no other starting dose is disclosed in B29. It would also regard this sentence as defining an embodiment of "the use invention", which is not limited to any particular TTS. This would provide a direct basis for the subject-matter of claim 1.

4.2.2 In the Board's view, this position is not tenable. The most straightforward and logical way of interpreting the wording "*the TTS of the invention*" (page 11, line 1) is to consider it to refer to the TTS defined on page 3, lines 5 to 7, and in claim 1. Indeed, as explained in paragraph 3.3 above, this TTS represents the core of the invention disclosed in B29 and is the subject of claim 1 of B29.

Any other interpretation based on the assumption that "*the TTS of the invention*" is not the one in claim 1 seems much less logical, and in any case, such an interpretation could not invalidate the most logical one. Thus, in the best-case scenario for the appellants, there could be a second interpretation based on the assumption that "*the TTS of the invention*" is not the one in claim 1 but is "any TTS". That would imply that the sentence on page 11 is ambiguous in that it is open to various interpretations. However, using an ambiguous sentence as a basis for the subject-matter of an amended claim (or a claim of a divisional application) is against the principle that this subject-matter should be derived in a an unambiguous manner from the (earlier) application.

4.2.3 "Derivation#2" has a further deficiency, namely the absence of any link to example IV. Therefore, the

appellants' argument that the "starting dose" referred to in the sentence on page 11 is the one of example IV is not based on an objective interpretation of this sentence. If, for the sake of argument, it is accepted that the skilled team would establish a link between page 11 and example IV, there would still be the problem that example IV relates to the use of a specific TTS which is a TTS according to claim 1 of B29. Thus, it could still not be concluded that the sentence of page 11 relates to a structurally undefined TTS providing the same release as the TTS#2 of 5 cm^2.

4.2.4 In the light of the considerations set out above, the Board concludes that the first paragraph of page 11 of B29 does not provide a basis for the subject-matter of claim 1 either.

4.3 It follows that the patent does not meet the requirements of Articles 123(2) and 76(1) EPC.

AUXILIARY REQUESTS 1 to 7

5. Each of these requests relates to a rivastigmine-based TTS which is not structurally defined and is characterised by providing the same starting dose a the TTS of 5 cm^2 used in the experiments of example IV.

The considerations set out in respect of the main request apply to the auxiliary requests too. Thus, auxiliary requests 1 to 7 are likewise considered to contravene Articles 123(2) and 76(1) EPC.

In view of the above, the Board does not need to decide on the admissibility of auxiliary requests 4 to 7.

REQUEST FOR REIMBURSEMENT OF THE APPEAL FEE

6. As the appeal is not allowed, the appellants' request for reimbursement of the appeal fee has to be rejected, Rule 103(1)(a) EPC.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. The request for reimbursement of the appeal fee is rejected.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated